Batch Release Certificate

Product name: **Dextran 1 EP/USP**

Specification No.: **40082**

Batch No.: xxxxxx
Manufacturing date: mmmm_yyyy
Retest date (3 years): mmmm_yyyy

Manufacturing sites: Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark
DKMA No.: 254629
GMP certificate No.: DK API-H 10000578, DK API-V 10000639
FDA establishment No.: FEI 3002807874
FDA facility classification: Acceptable
EDQM certificate No.: R1-CEP 2003-165-Rev 01

Method:	Parameter:	Results of analysis:		Limits:
Visual	Appearance of powder:	Complies	*	White or almost white hygroscopic powder
EP	Color of solution (Absorbance at 375 nm, 15% sol., 1 cm):	x.xx		≤0.12
EP	Specific rotation, (+/-) °:	+x		+148 – +164
USP	Specific rotation, (+/-) °:	+x		+148 – +164
USP	Infrared Absorption:	Complies	**	Complies
USP	pH (15% solution):	x.x		4.5 – 7.0
EP	Average molecular mass, Mw:	x,xxx		850 – 1,150
EP	<3 glucose units fraction, %:	x		<15
EP	>9 glucose units fraction, %:	x		<20
USP	Alcohol and related impurities:	Complies	**	Complies
EP	Nitrogen containing substances, ppm N:	x		≤110
EP	Sodium chloride, % w/w:	x.x		≤1.5
EP	Loss on drying (105°C, 5h), % w/w:	x.x	***	≤5.0
USP	Loss on drying (105°C, 5h), % w/w:	x.x	***	≤5.0
EP	Bacterial endotoxins, IU/g:	Complies	¤	<25
EP/USP	Microbial contamination (TAMC), cfu/g:	Complies		≤100
USP	Microbial contamination (TYMC), cfu/g:	Complies		≤10

References to official monographs are to be considered as current editions.

EDQM refers to 'European Directorate for the Quality of Medicines and Healthcare'. DKMA refers to 'Danish Medicines Agency'

*) Very soluble in water, very slightly soluble in ethanol (96%).

**) Test is not carried out routinely.

***) Due to the hygroscopic nature of the powder, loss on drying may change during storage. We recommend keeping small container well closed and protected against moisture in alu bag.

¤) Determined by turbidimetric kinetic method.

We confirm that no class 1, class 2 and class 3 solvent, cf. EP 5.4 Residual solvents, is used in the manufacturing of this product.

We confirm that no metal catalysts or metal reagents are used in the manufacturing of this product. Elemental impurities, cf. ICH Q3D are unlikely to be present.

CERTIFICATE OF CONFORMITY

I hereby certify that the above information is authentic and accurate. This batch of Active Pharmaceutical Ingredient has been manufactured, including packaging and quality control at the above mentioned site in full compliance with the GMP requirements for active starting materials and with the above mentioned specifications. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Date (dd.mm.yyyy):

Qualified Person, Heidi Skjødt Andersen, M.Sc. Pharm

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